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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,965	11/14/2003	Charles H. Pugsley	06530.0288-01	7789
22852	7590	01/09/2008		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 01/09/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/706,965

Applicant(s)

PUGSLEY ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,11-38 and 40-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,25 and 466 is/are allowed.
- 6) ☐ Claim(s) 1,2 6-9, 11-24,37-38, 40-45 and 47-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 4/12/2007 in which claim 1 and 37 were amended and new claims 47-57 were added. Currently claims 1,2 6-9, 11-38 and 40-57 are pending for examination in this application.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 10/12/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Double Patenting

Claims 1,2 6-9, 11-38 and 40-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-98 of copending Application No. 10/428801. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose a broader claim scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 6-7, 11-12, 16-24 and 37-46 are rejected under 35 U.S.C 103(a) as being unpatentable over Eckert et al. (5,487,889) in view of Widemire (5,782,788). Eckert et al. disclose a bandage for continuous application of biologicals.

Regarding claims 1-2, 6-7, 11-12, 16-24 and 37-46, Eckert et al. discloses a tissue patch (10) capable of treatment of a lesion in an alimentary tract of a patient, comprising: a tissue implant (16) comprising a cellular suspension of genetically engineered cells or a cellular growth layer having a top surface and bottom surface; and a substrate completely surrounding the tissue (21, 12, 15) (Figures 1-5). , Eckert et al. discloses that the tissue patch (10) that uses an adhesive backing for securement (col 6, ln 10-65). Eckert et al. further discloses that the cells produce a therapeutic growth hormone agent that diffusion through the substrate (50) by the cells growing at a predetermined depth for proper release of the hormone agent, wherein the implant is capable of being folded and expanded upon delivery to an agent site.

Eckert et al. meets the claim limitations as described above except for the protective liner and adhesive surface area components.

However, Widemire teaches a wound dressing.

Regarding claims 1-2, 6-7, 11-12, 16-24 and 37-45, Widemire teaches a tissue implant (220) device with a tissue implant (228) attached to the first surface occupying a first area of the first surface of the substrate with a therapeutic agent (28), a removably protective liner (30) attached to the first surface to cover the tissue implant, and an adhesive (24) that occupies a second surface than that of the tissue implant (220) which is defined as the outer edge of the first surface of the substrate and is configured to hold the patch to a lesion surface (cols 1-2, Figure 5). The trans-dermal patch is capable of being folded and unfolded to aid in its positioning (Figures 5).

At the time of the invention, it would have been obvious to add the adhesive and the protective liner of Widemire to the system of Eckert et al. in order to protect the adhesive base and maintain sterility prior to securement to the patient (see abstract). The references are analogous in the art of wound treatment and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Widemire (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 8-9, 13-14, and 47-57 are rejected under 35 U.S.C 103(a) as being unpatentable over Eckert et al. in view of Widemire. The modified Eckert et al. meets the claim limitations as described above except for the specific adhesive and substrate material.

Regarding claims 8-9, 13-14, and 47-57 it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the substrate out of a bio-asorable gel attached with a cyano-acrylate adhesive in order to make the device as biocompatible as possible, since it has been held to be within the general skill of a worker in the art to select a known material (see Gruskin 5,502,042) on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Allowable Subject Matter

Claims 25-36 and 46 allowed.

Response to Arguments

Applicant's arguments filed 10/12/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Eckert et al. (5,487,889) in view of Widemire (5,782,788) does not disclose the protective liner removably attached to the substrate with the references teaching away from this claimed limitation.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the limitation of the claimed subject matter is a functional limitation. Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from

a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Examiner further asserts that Applicant's own drawings do not disclose the argued recitation as shown in the reproduced figure below. As shown below, the protective liner does not have any direct contact with the implant.

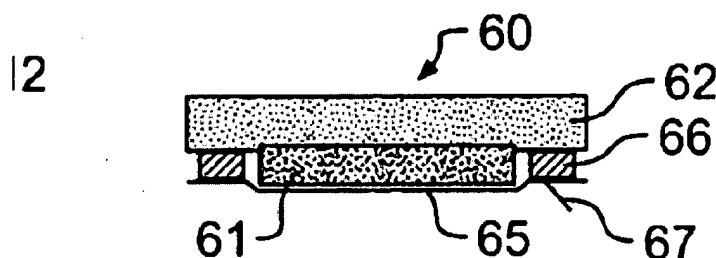


FIG. 2B

Additionally, the cellular substrate of Eckert et al. can be a solid layer or be a suspension that is injected into the bandage membrane, to which a the protective liner can be applied.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Date:

1/7/06



Christopher D. Koharski
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